April 3, 2003

Frank L. Lambert
Environmental and Technical Director
MeadWestvaco Corporation
3950 Faber Place Drive
North Charleston, SC 29405

Dear Mr. Lambert:

The Office of Pollution Prevention and Toxics is transmitting EPA's comments on the robust summaries and test plan for 2-cyclohexene-1-octanoic acid, 5(or 6)-carboxy-4-hexyl posted on the ChemRTK HPV Challenge Program Web site on December 4, 2002. I commend MeadWestvaco Corporation for its commitment to the HPV Challenge Program.

EPA reviews test plans and robust summaries to determine whether the reported data and test plans will provide the data necessary to adequately characterize each SIDS endpoint. On its Challenge Web site, EPA has provided guidance for determining the adequacy of data and preparing test plans used to prioritize chemicals for further work.

EPA will post this letter and the enclosed comments on the HPV Challenge Web site within the next few days. As noted in the comments, we ask that MeadWestvaco Corporation advise the Agency, within 60 days of this posting on the Web site, of any modifications to its submission.

If you have any questions about this response, please contact Richard Hefter, Chief of the HPV Chemicals Branch, at 202-564-7649. Submit questions about the HPV Challenge Program through the "Contact Us" link on the HPV Challenge Program Web site pages or through the TSCA Assistance Information Service (TSCA Hotline) at (202) 554-1404. The TSCA Hotline can also be reached by e-mail at tsca-hotline@epa.gov.

I thank you for your submission and look forward to your continued participation in the HPV Challenge Program.

Sincerely,

-S-

Oscar Hernandez, Director
Risk Assessment Division

Enclosure

cc: C. Auer
A. Abramson
W. Penberthy
M. E. Weber

EPA Comments on Chemical RTK HPV Challenge Submission:
2-Cyclohexene-1-Octanoic Acid, 5(or 6)-Carboxy-4-Hexyl

Summary of EPA Comments

The sponsor, MeadWestvaco Corporation, submitted a test plan and robust summaries to EPA on November 20, 2002 for 5(or 6)-Carboxy-4-hexyl-2-cyclohexene-1-octanoic acid (CAS No. 53980-88-4). EPA posted the submission on the ChemRTK HPV Challenge Website on December 4, 2002.

EPA has reviewed this submission and has reached the following conclusions:

1. Physicochemical Properties. EPA agrees with the submitter's approach. The submitter needs to explain its conclusions for some endpoints in the appropriate robust summary fields.

2. Environmental Fate. EPA agrees that all appropriate SIDS-level endpoints have been addressed for the purposes of the HPV Challenge Program. The submitter needs to provide additional information and address some deficiencies in the robust summaries.

3. Health Effects. Adequate data are available for acute and genetic toxicity endpoints for the purposes of the HPV Challenge Program. EPA agrees with the submitter's proposal to conduct a combined repeated-dose/reproduction/developmental toxicity screening test.

4. Ecological Effects. Adequate data are available for fish, aquatic invertebrate, and aquatic plant toxicity endpoints for the purposes of the HPV Challenge Program.

EPA requests that the submitter advise the Agency within 60 days of any modifications to its submission.

EPA Comments on the 5(or 6)-carboxy-4-hexyl-2-cyclohexene-1-octanoic Acid Challenge Submission

Test Plan

Test Substance

The substance is commercially available as Westvaco DIACID® 1550 (a mixture of 60-70% of the C-21 diacid, 20-25% unreacted C-18 monoacid, and 5-10% C-36 dimer acid) and is described as a Class 2 product. EPA agrees with the submitter's plan to use Westvaco DIACID® 1550 as the test substance.

Physicochemical Properties (melting point, boiling point, vapor pressure, partition coefficient and water solubility)

The submitter's approach for these endpoints is adequate for the purposes of the HPV Challenge Program. While EPA agrees that testing is unnecessary for melting point, boiling point, and vapor pressure for the specific reasons in the test plan, the submitter needs to state these reasons in the robust summary fields for these endpoints.

Environmental Fate (photodegradation, stability in water, biodegradation, fugacity)

EPA agrees with the submitter's conclusion that testing is unnecessary for photodegradation, stability in water, and fugacity endpoints for the specific reasons provided in the test plan. However, the submitter needs to state these reasons in the robust summary fields for these endpoints.

Biodegradation. The submitter has provided data from a ready biodegradability test for the commercial product Westvaco DIACID® H-240, a 40% solution of the potassium salt of Westvaco DIACID® 1550. Although the data from an OECD ready biodegradability test appear adequate, the submitter needs to identify the components of the mixture that are biodegradable or provide additional information on the loss of individual components or structurally similar groups of compounds over the course of the test period.

Health Effects (acute toxicity, repeated-dose toxicity, genetic toxicity, and reproductive/developmental toxicity)

Adequate data are available for acute and genetic toxicity endpoints for the purposes of the HPV Challenge Program. EPA agrees with the submitter's proposal to conduct a combined repeated-dose/reproduction/developmental toxicity screening test to address these endpoints.

Ecological Effects (fish, invertebrates, and algae)

Adequate data are available for fish, aquatic invertebrate, and aquatic plant toxicity endpoints for the purposes of the HPV Challenge Program.

Specific Comments on the Robust Summaries

Environmental Fate

Biodegradation. The submitter needs to provide information on the components of the mixture that are biodegradable and clarify the source of the inoculum and what, if any, adaptation or pre-acclimation steps were used prior to the screening test.

Followup Activity

EPA requests that the submitter advise the Agency within 60 days of any modifications to its submission.